Case 1:19-md-02875-RMB-SAK Document 1793-22 Filed 12/01/21 Page 1 of 4 PageID: 50071

Exhibit 23

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1
      IN THE UNITED STATES DISTRICT COURT
        FOR THE DISTRICT OF NEW JERSEY
2
                CAMDEN VICINAGE
3
    IN RE: VALSARTAN, : MDL NO. 2875
4
    LOSARTAN, AND
    IRBESARTAN PRODUCTS
                               CIVIL NO.
5
                               19-2875
    LIABILITY LITIGATION
                              (RBK/JS)
6
    THIS DOCUMENT APPLIES :
                               HON. ROBERT
    TO ALL CASES
                               B. KUGLER
7
8
           - CONFIDENTIAL INFORMATION -
           SUBJECT TO PROTECTIVE ORDER
9
10
11
                   May 7, 2021
12
13
14
           Videotaped remote deposition of
   LANCE R. MOLNAR, Ph.D., taken pursuant to
15
   notice, was held via Zoom
   Videoconference, beginning at 9:03 a.m.,
   EST, on the above date, before Michelle
16
   L. Gray, a Registered Professional
17
   Reporter, Certified Shorthand Reporter,
   Certified Realtime Reporter, and Notary
18
   Public.
19
20
21
          GOLKOW LITIGATION SERVICES
       877.370.3377 ph | 917.591.5672 fax
22
                 deps@golkow.com
23
24
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1 Understood. Okay. So let Ο. 2 me see if I get this straight. 3 So if something is -- so 4 you're saying that threshold versus 5 non-thresholded is a function of how a 6 particular genotoxic compounds exerts its 7 toxicity? 8 A. It doesn't have to be just 9 genotoxic. It's just how the -- the 10 mechanism through which a compound exerts 11 its toxicity, yes. Or its beneficial 12 effects. It doesn't matter. I think 13 that's what a threshold is, right. So... 14 Right. So what does it mean Ο. 15 for a -- in the context of a genotoxic 16 compound for it to be non-threshold? 17 Well, something that doesn't 18 exist. That's kind of what I'm pointing 19 out is there's no such thing as a -- that 20 I know of, or that we know of, that is a 21 non-thresholded effect; i.e., a 22 non-threshold effect would mean that a 23 single molecule could be detrimental, 24 right? There's no threshold of exposure

- 1 You can treat them however you want.
- The EMA, FDA, ICH, you know,
- ³ regulatory bodies in general, have
- 4 decided that that's how they are going to
- ⁵ treat them. That's their expectations
- ⁶ for deriving limits for them will be.
- ⁷ I think the first kind of --
- 8 what's the word? The first guidance
- ⁹ document to that effect is the one that
- 10 you have on the screen now, from the EMA,
- 11 and that approach to consider them non --
- 12 as being a non-thresholded mechanism has
- 13 continued to this point.
- Q. And so -- okay. Thank you
- 15 for that.
- And so for -- back to this
- 17 guidance document and the statement that
- ¹⁸ nitrosamines are of such high potency
- 19 that they have to be excluded from the
- ²⁰ TTC approach.
- What do you understand that
- 22 to mean?
- MR. TRISCHLER: Objection to
- 24 form.